Insight

# Senate Finance Proposes Reforms to Medicare and Medicaid Drug Policy

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**Executive Summary**

- The Senate Finance Committee's drug-pricing bill, which the full Senate is expected to consider soon, is the latest effort from Congress to bring down the cost of prescription drugs.
- This bill does myriad things, including encouraging the use of biosimilars, penalizing drug manufacturers for price growth faster than inflation, and capping out-of-pocket expenses for Medicare Part D beneficiaries.
- While the ultimate impact of these changes is impossible to know, it is likely that some provisions would encourage higher launch prices for new drugs, while others could encourage greater use of less expensive medicines and eliminate the incentive for hospitals to take over independent doctors' offices.

**Introduction**

The Senate Finance Committee recently marked up a package of legislative reforms to Medicare and Medicaid drug reimbursement. The package—designed to reduce government and beneficiary spending on drugs as well as reduce drug prices themselves—eventually garnered bipartisan support after a lengthy debate. Senators filed more than 100 amendments, and the committee adopted 21 of them, although Chairman Grassley and Ranking Member Wyden both expressed interest in including additional amendments in the final package before it reaches the Senate floor. The package includes such provisions as offering providers financial incentives for the use of biosimilar products (rather than the brand-name reference product), imposing significant penalties on drug makers if the price of their drug rises faster than inflation, and capping the out-of-pocket (OOP) expenses for Medicare Part D beneficiaries on their retail prescription drug costs.

**Medicare Part D**

The government spends significantly more on prescription drugs under the Medicare Part D program than under other programs—roughly $100 billion in 2018, covering more than 43 million beneficiaries. Reforms here therefore promise to have a large impact on overall drug spending.

*Benefit redesign*

The most significant change in the Finance Committee bill is the restructuring of the Part D benefit design, as outlined in Section 121. The reforms include three key components: imposing an OOP cap on beneficiary spending; eliminating the existing manufacturer Coverage Gap Discount Program and replacing it with a mandatory manufacturer discount in the catastrophic phase; and changing the liability of insurers and the government in the catastrophic phase. This design is similar to one previously proposed by the American Action Forum (AAF)

, though the proportions of the various parts have shifted, which will alter the impact relative to AAF's proposal. The intent of the redesign is to increase the incentives of drug manufacturers and insurers to control drug spending by making them liable for more of the costs.

Under the Finance Committee proposal, beneficiaries would continue to have a deductible period, during which they would be responsible for 100 percent of the costs. Then, in the initial coverage phase, beneficiaries would be responsible for 25 percent of costs; insurers would pay the remaining 75 percent until the beneficiary reaches the OOP cap. The cap would be set at $3,100, beginning in 2022, and then indexed to the rate of growth in Part D spending. Once beneficiaries have reached that cap, they would move into the catastrophic phase and no longer be liable for any costs incurred. If beneficiaries then take a brand-name or biosimilar drug, the manufacturer would be required to pay a 20 percent rebate for any cost in the catastrophic phase (if beneficiaries take a generic, however, their percentage drops to zero). Insurers would be responsible for 60 percent of all costs incurred in the catastrophic coverage phase, up from the 15 percent they currently pay. The federal government—which currently pays 80 percent of all costs in the catastrophic phase—would pay 20 percent of the costs when a beneficiary takes a brand-name or biosimilar drug and would pay 40 percent when a generic drug is taken.

*Price inflation penalty*

Drug manufacturers would also be subject to an inflation rebate penalty for Part D drugs under Section 128 (similar to the penalty Section 107 imposes on Part B drugs; see below). Unlike the Part B provision, however, which uses the drug's price net of rebates, in Part D the applicable drug price will be the drug's wholesale acquisition cost (WAC), which is the list price. Using WAC to determine inflation penalties is therefore likely to result in fewer rebates (which were valued at 25.3 percent of Part D drug costs in 2018) and thus increased net prices for existing drugs. Launch prices for new drugs may be higher, also, as a result of this policy. Knowing that there will be a penalty for price *increases* but not *high* prices creates an economic incentive to set the initial price higher than what otherwise would have been expected to lessen the need to raise prices in the future and potentially trigger the inflation penalty.

*Public disclosure and information provided to MedPAC and MACPAC for research*

Sections 122, 123, and 124 would increase the disclosure of drug pricing information—currently required to be shared with the Department of Health and Human Services (HHS)–both to the public and to congressional advisory committees, specifically the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment Advisory Commission (MACPAC). Various drug pricing and pharmacy benefit manager (PBM) information, including aggregate rebate and discount values, PBM's pharmacy reimbursement rates relative to insurer costs for PBM services, and prescription dispensing rates would be required to be publicly disclosed, but on a 2-year lag. More detailed pricing and rebate information would be required to be shared with MedPAC and MACPAC. Part D plans would also be required to have third-party audits of their PBM contracts every 2 years to ensure, among other things, appropriate accounting of net price for drugs. Part D plans would also be required to report to pharmacies any post-point-of-sale price adjustments. Finally, in order to ensure that projected direct and indirect remuneration (DIR) for the upcoming year is based on actual DIR in the prior year, plan sponsors would be required to report actual and projected DIR amounts annually, beginning in 2022.

*Real-time benefit tools*

In order to allow doctors and patients to make more informed decisions regarding potential treatment options,

Section 125 would require that Part D plan sponsors enable providers to access a real-time benefit tool (RTBT) through their electronic health record (EHR) system that details an enrollee's prescription drug coverage. The RTBT should provide the enrollee's formulary and benefit information, including cost-sharing information for a particular drug and a list of clinically appropriate alternatives; pharmacy information; and any prior authorization or other utilization management requirements. Providers would be required to ensure their EHR system supports RTBT functionality. This may reduce the number of prescriptions abandoned at the pharmacy counter, which is when a patient typically learns the price they are expected to pay OOP.

*Provision of Parts A and B claims data to drug plans*

Section 126 would modify a policy included in the Bipartisan Budget Act (BBA) of 2018, which allowed for Part D plan sponsors to access an enrollee's Medicare Parts A and B claims data. The BBA allows plan sponsors to use the claims data to improve medication use, to improve care coordination, and for other purposes; plan sponsors, however, were prohibited from using the data to inform coverage determinations. This section would provide an exception that allows insurers to use the data for certain coverage determinations if it will improve therapeutic outcomes, effective January 2021.

*Encouraging biosimilar use*

Section 132, added via an amendment by Senators Cassidy and Menendez, would add a new quality measure to the Part D Star Rating system assessing how a plan's benefit and formulary design encourages patient access to biosimilars—generic-like versions of biological products. Given the importance of the Star Ratings, this could provide a strong incentive for plans to change their formularies and encourage biosimilar utilization. Increasing market share is critical for continued investment in the biosimilar industry.

**Medicare Part B**

Just under a quarter of all Medicare drug spending is for physician-administered drugs covered under Medicare Part B. These are drugs provided in a doctor's office or other outpatient setting, as opposed to retail prescription drugs that are picked up at a pharmacy and self-administered. Some of the most common types of physician-administered drugs include chemotherapies, immunotherapies, and treatments for rheumatoid arthritis, Crohn's disease, and other inflammatory diseases.

*Reducing the payment rate for the initial 6 months that a drug is on the market*

Physicians administering drugs in their office—those covered under Part B—must first purchase the drugs themselves. They are then reimbursed for the drug, generally, at the average sales price (ASP) of the drug in the private sector plus 6 percent.[1] The ASP reimbursement system operates on a two-quarter lag, though, because it takes time for the pricing information (which must account for all discounts and rebates provided in the private sector) to be reported. Thus, during the first two quarters that a drug is available, there is no ASP data. Instead, drugs are initially covered based on WAC, which MedPAC has found to be significantly higher than ASP for most drugs.[2] Until January 2019, the payment rate for new drugs was WAC plus 6 percent; through rulemaking, the Centers for Medicare & Medicaid Services (CMS) changed the payment rate to WAC plus 3 percent, as MedPAC recommended, at the start of this year. Section 103 of the Finance Committee bill would essentially codify this change, establishing a maximum add-on payment of no more than 3 percent of WAC when ASP data is unavailable.

*Increasing the payment rate for biosimilars for the first 5 years they are on the market (after the ASP has been established)*

Payment for biosimilars under Part B similarly uses the ASP system, but with an important distinction. Originally, all biosimilars of a given reference product were reimbursed equally, with the base payment amount based on the ASP of all the biosimilars, but the 6 percent add-on payment equal to the add-on payment for the reference product. As explained here, this formula provided a reimbursement amount that was less than that provided for the innovator drug (saving money for Medicare) while not disincentivizing providers from using the lower-cost drug (because the add-on payment was the same as that for the higher-priced drug). Critics complained, however, that biosimilars should not be reimbursed this way since one biosimilar may treat different or fewer indications than another biosimilar of the same reference product. In response to this criticism, CMS issued a new regulation in November 2017 that provides a separate billing code and reimbursement amount for each biosimilar, using each individual drug's own ASP for the base payment amount and maintaining the use of the reference biologic's ASP for the add-on payment. During the initial two quarters of a biosimilar's availability, such products are paid just like other new drugs to market: 103 percent of WAC.

Section 104 of the bill would establish a new initial payment rate for biosimilars, effective July 2020: the lesser of either the biosimilar's WAC plus 3 percent or ASP plus 6 percent of the reference biologic. Section 105 would then alter a biosimilar's payment rate after that initial period for the next 5 years, effective January 2020. Once ASP for a biosimilar has been established, the reimbursement rate will be 100 percent of the biosimilar's ASP plus 8 percent of the reference product's ASP (as opposed to the current 6 percent add-on rate) for a 5-year period, although the Menendez-Carper amendment, which was adopted, would limit the add-on payment to no more than the *total* payment amount for the reference biologic.

This temporary increased payment rate would offer providers a financial incentive to use the biosimilar, which is intended to help biosimilar products gain market share. The hope is that when the payment rate returns to what it otherwise would have been, providers and patients will be used to the biosimilar and will maintain treatment with the biosimilar. It is possible, though, that this change could increase beneficiary spending slightly: Beneficiaries pay their co-insurance (20 percent) based on the Medicare reimbursement rate; if the reimbursement rate increases from a 6 percent add-on to 8 percent, beneficiary co-insurance liability will increase by 0.4 percent.

*Inclusion of the value of coupons provided to privately insured patients in the calculation of ASP*

As previously mentioned, the ASP must account for all discounts and rebates offered to private insurers. One caveat is that these discounts do not include the value of any coupons that drug manufacturers may provide directly to patients to reduce their OOP costs for a drug. Section 102 would require that a drug's ASP be reduced by the value of any coupons provided by manufacturers to privately insured patients (such coupons are prohibited from being provided to Medicare beneficiaries). While this change is expected to reduce Medicare reimbursement rates (and beneficiary co-insurance), such an outcome will only be achieved if manufacturers continue to offer such coupons; it is possible that this policy change could discourage their continued use.

*Maximum add-on payment for physician-administered drugs*

Section 110 would limit a drug's add-on payment amount to $1,000, beginning in January 2021 through December 2028. In 2029 and each year thereafter, the maximum amount would be indexed to the consumer price index for urban consumers (CPI-U).

*Price inflation penalty*

Section 107 would add a new price control measure requiring any brand-name drug manufacturer to pay a rebate for each drug provided under Part B if the ASP (net price) of the drug increases faster than inflation. The price of a drug would be assessed quarterly, relative to the "payment amount benchmark," which would be the price of existing drugs on July 1, 2019; for new drugs, the benchmark would be the first day the drug is marketed. The rebate required would be equal to the amount by which the ASP in a given quarter exceeds the "inflation-adjusted payment amount" for each drug provided during the quarter (unless the drug was provided for end-stage renal disease or the manufacturer already paid a 340B discount or Medicaid drug rebate).

While this measure is likely to be effective in stopping net price increases for existing drugs beyond the rate of inflation, it may allow for continued growth in list prices and exacerbate the "gross-to-net bubble." It is also very likely to encourage higher launch prices for new drugs, just as is expected with Part D drugs. Ultimately, it is possible that the short-term gains from this policy may be more than offset by the long-term costs.

*Refunds for unused drugs*

Section 108 would attempt to decrease some of the waste in the health care system by requiring certain manufacturers to provide a refund for unused drugs. Many Part B drugs are provided via single-use vials; oftentimes, a patient will not need all of the drug provided in a vial, but any unused amount is unable to be saved and used on the next patient. Accordingly, Medicare typically reimburses providers for each vial used, but as a result, Medicare is wasting money paying for substantial amounts of drugs that are unused. This bill would require drug manufacturers to provide a refund to Medicare for unused portions of drugs provided in single-dose vials if the unused amount exceeds a minimum threshold of 10 percent. The refund amount would be equal to the portion of the cost attributable to any unused amount in excess of the 10 percent allowance. This provision would apply to all drugs, biologics, and biosimilars, except radiopharmaceuticals and imaging agents, beginning in July 2021. Presumably, manufacturers will choose, as a result of this change, to produce vials which more closely match a common usage amount, while still allowing for variance depending on a what is best for each patient.

*Site-of-service transparency and site-neutral payments*

In addition to the reimbursement for the drug itself, providers are also reimbursed an administrative fee for the cost and labor of administering the drug. Historically the site of service and the corresponding payment system for that site determined the fee. Recent laws worked to impose a uniform service fee across sites of service to eliminate pay disparities and decrease the incentive for hospitals to acquire physician offices and build off-campus hospital outpatient departments (HOPDs). These recent laws grandfathered in existing HOPDs, however, and they continue to be paid the higher outpatient prospective payment rates. Section 111 would end the grandfathered status, such that all physicians are reimbursed equally under the physician fee schedule for the administration of a drug.

**Medicaid**

The federal government also pays roughly $30 billion for prescription drugs provided to Medicaid beneficiaries, and it has implemented rules to help ensure Medicaid pays the least for prescription drugs of any provider in the country.

The Medicaid Drug Rebate Program (MDRP) requires drug manufacturers, as a condition of having Medicaid cover their drugs, to pay a rebate for all of their outpatient prescription drugs, including biologics, taken by Medicaid beneficiaries. The amount of the required rebate is set by law such that the net price of the drug is either equal to the best price available to anyone in the private market or equal to a certain percentage of the drug's average manufacturer price (AMP)—whichever gives Medicaid the lowest price. The percentage for this rebate varies by type of drug, with brand-name drugs requiring the greatest rebate. An additional rebate must also be paid if a drug's list price increases at a rate greater than inflation; this additional rebate is equal to the amount by which the price increase exceeds the rate of inflation, measured by the CPI-U.

*Ensuring accuracy of price and rebate information*

Section 204 would provide the Secretary of HHS with new oversight authority and impose new reporting requirements on drug manufacturers in order to improve the accuracy of price and product information under the MDRP. The Secretary would be required to audit price and product information and would be empowered to survey various entities in the supply chain to verify the accuracy of pricing information. Civil monetary penalties could be issued for noncompliance, and the Secretary would be required to submit to Congress a report detailing any additional authority needed. The federal government currently has limited authority to enforce compliance with the MDRP. Manufacturers are responsible for reporting all necessary pricing, sales, and product information to CMS. If information provided is not accurate or not provided in a timely fashion, manufacturers may face civil monetary penalties.[3] If manufacturers violate the terms of the agreement, they may also be terminated from the program.[4] The federal government is unlikely to use this penalty, however, since doing so would result in beneficiaries (including Part B beneficiaries) losing access to all drugs produced by that manufacturer. Regarding potential misclassifications of a drug (whether listed as a brand-name drug or a generic), CMS currently has no authority to require correct classification or to penalize manufacturers who fail to do so.[5] An investigation by the HHS Inspector General found that the misclassification of products has resulted in more than $1.3 billion in lost rebates between 2012 and 2016.[6]

*Excluding authorized generics from calculation of AMP*

Section 205 would exclude authorized generics from being included in the calculation of AMP. Under current law, any existing "authorized generic" must be taken into account when determining the rebate amount for a brand-name drug under the MDRP.[7] An authorized generic drug is an exact copy of a brand-name drug (having both the same active *and* inactive ingredients) but sold at a lower price and with a different name than the brand-name drug.[8] A manufacturer of a brand-name drug may choose to sell (or authorize the sale of) an authorized generic version to maintain market share once the market exclusivity period for its brand-name drug expires. When the price of an authorized generic is included in the AMP of the brand-name drug and that price is lower than the price of the brand-name drug, its inclusion will have the effect of lowering the AMP, which in turn will reduce the amount of the rebate and increase Medicaid's net price for the drug.

*Increasing the maximum rebate amount to 125 percent*

Section 209 would increase the maximum rebate amount under the MDRP to 125 percent of a drug's average manufacturer price. Under current law, the maximum rebate amount that a drug manufacturer would have to

provide to the Medicaid program (inclusive of the inflationary rebate) is limited to 100 percent of the drug's AMP. Some have claimed that by limiting the total rebate that must be paid, drug manufacturers are able to increase the cost of their drug with limited repercussions beyond providing product at no cost to Medicaid. Removing this cap, however, would result in drug manufacturers possibly having to pay—rather than be paid—for the use of their drugs in Medicaid. As explained here, this change could worsen, rather than mitigate, the problem it is intended to fix by creating incentives for higher launch prices and less negotiation (to increase a product's "best price") in other markets. Any policy to increase the mandatory rebate amount will exacerbate the existing problems with this program.

*Expanding the MDRP to drugs provided in outpatient hospital services*

Under Section 210, states would have the option of extending the requirements of the MDRP to any drug, biologic, or insulin product included as part of a bundled payment if it is provided in an outpatient setting. Under current law, such drugs are only subject to the MDRP if they are paid for separately from any other services; in other words, products covered under a single bundled payment for a given service are excluded from the rebate requirements right now, but this reform would allow states to include them.

*Banning spread pricing*

Section 206 would ban what is known as "spread pricing" in PBM contracts with pharmacies when dispensing drugs to Medicaid beneficiaries. This provision would require that the full payment amount that a PBM receives from a Medicaid Managed Care Organization for a drug provided to an enrolled beneficiary be fully passed on to the pharmacy that dispenses the drug. Any payments to PBMs for pharmacy management services must be limited to the ingredient cost of the drug and a professional dispensing fee at least equal to what the state would pay for a fee-for-service beneficiary. PBM administrative fees would be limited to a "reasonable" amount (with "reasonable" left undefined). The HHS Secretary would also be required to conduct a survey of retail community pharmacy prescription drug prices and make their findings publicly available.

*Risk-sharing value-based agreements for covered outpatient drugs*

Section 208 would allow states to enter into risk-sharing value-based agreements with manufacturers of certain drugs beginning in January 2022. The types of drugs that would qualify for this allowance are gene therapies that are expected to need no more than three administrations. Under this type of agreement, the state would be able to make payment installments over the course of up to 5 years. Payments may be reduced if relevant clinical outcomes are not achieved. The state would be required to continue making the obligated payment installments, even if the beneficiary is no longer enrolled in the state's Medicaid program, although there would be an exception if the patient dies. Importantly, the payment amount under these agreements would not affect the drug's "best price" for purposes of determining the required Medicaid rebate. If the CMS Office of the Actuary finds that the spending for a drug is more than under such an agreement than it otherwise would have been, the contract may be cancelled and the manufacturer would be obligated to repay the difference to the state and federal government.

**Miscellaneous**

*Manufacturer price transparency and justification*

Under Section 141, beginning in July 2022 drug manufacturers would be required to report information and

supporting documentation needed to justify certain list price increases for certain prescription drugs. Drugs costing at least $10 per dose would trigger this requirement if the list price doubles in a single year, increases by at least 150 percent in 2 years, 200 percent in 3 years, 250 percent in 4 years, or 300 percent in 5 years. For existing drugs in the top 50 percent of net spending per dose in either Medicare or Medicaid in at least one of the preceding 5 years, this requirement would be triggered if, beginning in 2020, the list price increases at least: 15 percent in a single year, 20 percent in the prior 2 years, 30 percent in the prior 3 years, 40 percent in 4 years, or 50 percent in 5 years. Finally, for new drugs coming to market, the trigger would be any drug for which the list price for a year supply or course of treatment exceeds the gross spending amount necessary to meet the catastrophic coverage threshold for Part D (which is roughly $9,300 in 2020, based on current law).

Information that may be required includes the individual factors contributing to the price increase and the role that each factor plays, as well as manufacturer spending for materials, production, patents, licenses, and acquiring a drug from another company, if applicable. Manufacturers may also choose to provide information pertaining to research and development costs and the percentage of such costs derived from federal funds; total revenue and net profit from the drug; costs for marketing and advertising; and information relating to spending on drugs that ultimately failed to receive approval from the Food and Drug Administration. Failure to comply with these requirements would result in significant financial penalties.

**Conclusion**

This legislative package from the Senate Finance Committee is the last piece of a tri-committee effort in the Senate to produce a comprehensive legislative package on drug pricing. The Senate HELP and Judiciary Committees—as well as the House Energy and Commerce and Ways and Means Committees—have also passed legislation that, if it becomes law, will affect drug prices, the supply chain, and government and patient spending. It is expected that the proposals from all three Senate committees will be packaged together for a single vote on the Senate floor this fall. What will ultimately come of all this work is unknown, but the potential impact for beneficiaries, insurers, manufacturers, and the government is quite significant.

[1] Since 2011, as a result of the Budget Control Act of 2011 and sequestration, the 6 percent add-on payment has been reduced to 4.3 percent.

[2] http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

[3] Section 1927(b)(3)(C) of the Social Security Act

[4] Section 1927(b)(4)(B) of the Social Security Act

[5] https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf

[6] https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf

[7] Section 1927(k)(1)(C) of the Social Security Act

[8] https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbr